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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,131	10/14/2003	Maria Palasis	12013/47501	1273
23838	7590	06/22/2004	EXAMINER	
KENYON & KENYON 1500 K STREET, N.W., SUITE 700 WASHINGTON, DC 20005			MICHENER, JENNIFER KOLB	
			ART UNIT	PAPER NUMBER
			1762	

DATE MAILED: 06/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/684,131	Applicant(s) PALASIS ET AL.	
	Examiner Jennifer K. Michener	Art Unit 1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "roll coating" is confusing.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "roll coating" in claims is used by the claim to mean "rotating a stent on a holder", while the accepted meaning is a method of transferring a coating to a substrate by contact of the substrate with a coated roller. The term is indefinite because the specification does not clearly redefine the term.

Examiner notes that the claim does not require "roll coating" as is known in the art, but merely requires coating a stent as it is rotated on holder, which is well-known in the art, with the use of a conveyance system, which is an automated means of placing a stent within and removing a stent from a coating chamber.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 3, 4, 6, 16, and 18-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Schwarz et al. (6,730,349).

Schwarz teaches a method of coating a medical device, such as a stent, which has been placed on a holder which can be located on a conveyer, such that coating is applied to the stent as it is conveyed through the coating station. The vibration of the conveyer rotates (i.e., causes to turn or move about an axis or center) the stent and holder (claims 1, 11, 13; Figures; col. 17, lines 14-20). Schwarz teaches coating a plurality of medical devices and the use of a spray-coater (col. 15, line 53 and throughout). Based on the various nozzles of the spray coater (figure 6; col. 15, lines 5-15) and the rotation of the stents, the stents will be sprayed from a variety of directions. The stents of Schwarz are dried prior to removal of the stents from the holders (col. 13, lines 64-66) and coating and drying are repeated to form multiple layers in the method of Schwarz (col. 14, lines 53-58 and throughout). The injection of heat into the coating chamber would inherently heat the conveyer.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 2, 5, 7-13, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwarz.

Schwarz teaches that which is disclosed above, but fails to specifically teach that the rubber conveyer belt is an *endless* belt. However, Examiner notes that Schwarz teaches that the method can be used to continuously cycle medical devices through the coating chamber and Figure 6 shows that the conveyer does not end at either end of the coating chamber (col. 3, line 4; col. 14, lines 20-30; Figure 6). It is Examiner's position that the use of an endless belt would have been obvious to one of ordinary skill in the art running a continuous operation through a coating chamber with the expectation of successful non-stop coating operations, as required by Schwarz.

While Schwarz teaches spray-coating he fails to teach dip-coating, however it is Examiner's position that spray-coating and dip-coating operations are obvious variations useful in the coating art, particularly the coating of medical devices. Dip-coating stents, including stents on holders, is a well-known alternative method of coating, as disclosed within the instant specification. Therefore, it would have been obvious to one of ordinary skill in the art to interchange dipping for spraying in a method of coating medical devices with the expectation of similar, successful results.

Regarding claims 7-11, requiring spraying the stents from distances that are greater or less than the distance applied for the previous steps, one or a plurality of times, Examiner notes, as taught above, that Schwarz teaches multiple coating passes. Additionally, as shown in Figure 6 and the discussion thereof, there are a plurality of nozzles useful in the conveyer coating embodiment of Schwarz, which he teaches may

be spaced at varying elevations relative to the conveyer. Therefore it is Examiner's position that based on the teachings of Schwarz that varying elevations may be used relative to the conveyer loaded with stents, that the different spacing embodiments of Applicant would have been obvious to one of ordinary skill in the art such that one coating may be applied from a greater or lesser distance than the previously applied coating. Additionally, even if all nozzles were the same elevation, the bouncing of the devices in Schwarz could inherently position the stents, relative to the nozzles, at the varying distances required by Applicant. In the absence of a showing of criticality, the various elevations of nozzles of Schwarz would inclusive of the obvious variations of the various embodiments of Applicant.

Regarding claims 12-13, Applicant requires "automated" stent loaders and unloaders. Schwarz does not teach how the stents are inserted into or removed from their holders. However, it is well settled that it is not inventive to broadly provide a mechanical or automotive means to replace manual activity which has accomplished the same results. *In re Venner et al.*, 120 USPQ 192. The mere statement that a device to be operated automatically instead of by hand without a claim specifying any particular automotive mechanism is not a statement of the invention. *In re Rundell*, 9 USPQ 220.

Schwarz' stents rotate as they are bounced from the conveyer belt relative to the sprayer, however the reference does not teach rotating the sprayer relative to the stent. Examiner notes that movement is relative. It would have been obvious to move the

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sprayer relative to the stents instead of the stents relative to the sprayer with equivalent results.

9. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti (6,743,462) in view of Schwarz et al.

Regarding the independent claims, Pacetti teaches mounting a stent on a mandrel and spraying the stent, while rotating, with a coating agent (col. 3, lines 50-54).

What Pacetti fails to teach is the coating of a plurality of stents, simultaneously, through the use of a conveyer to convey stents into and out of the coating application area.

Schwarz et al. teach that which is disclosed above regarding the coating of a plurality of stents within holding devices through the use of a conveyer to convey the stents into and out of the coating application area.

Since Pacetti teaches mounting stents on stent holders and rotating while coating and Schwarz teaches mounting stents in stent holders and rotating while being moved via a conveyer through a coating system in order to continuously mass produce coated stents, Schwarz would have reasonably suggested the use of a conveyer to coat multiple stents in the method of Pacetti. It would have been obvious to one of ordinary skill in the art to use the teachings of Schwarz in the method of Pacetti to enable Pacetti to continuously coat stents without stopping and starting the operation to mass produce coated stents, which would optimize profits.

Regarding claims 14 and 15, Pacetti teaches the use of rotating mandrels, which qualify as "rolling pins ... sized to permit stent placement". Placement of stents onto holders would inherently require "handling devices".

Regarding the remaining dependent claims, Schwarz teaches the limitations in the rejections above.

Conclusion

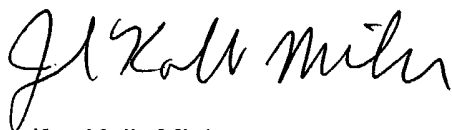
10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lukic (5,534,287) teaches rolling a stent on a coating surface. Fan (5,620,738) teaches roll-coating stents.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer K. Michener whose telephone number is (571) 272-1424. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 571-272-1415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "J Kolb Michener". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Jennifer Kolb Michener
Patent Examiner
Technology Center 1700
June 17, 2004